METHOD AND APPARATUS FOR PERCUTANEOUS REDUCTION OF ANTERIOR-POSTERIOR DIAMETER OF MITRAL VALVE

FIELD OF THE INVENTION

[0001] The present invention generally relates to a device and a method for treatment of mitral regurgitation occurring in the presence of structurally normal mitral leaflets. By causing pressure to be applied to the septal and lateral annulus of the valves the leaflets are coapted.

BACKGROUND OF THE INVENTION

[0002] Mitral regurgitation with structurally normal leaflets is generally caused by ischemic heart disease and dilated cardiomyopathy. The mitral apparatus is made up of four major structural components and includes the annulus, the two leaflets, the chordae and the papillary muscles. Improper function of any one of these structures or in combination can lead to mitral regurgitation. It is generally believed that acute mitral regurgitation due to myocardial ischemia results from discordant function of the papillary muscles. Annular dilation is a major component in the pathology of mitral regurgitation regardless of causes and is manifested in mitral regurgitation related to dilated cardiomyopathy and chronic mitral regurgitation due to ischemia.

[0003] The mitral valve is intended to prevent the regurgitation of blood from the left ventricle into the left atrium when the left ventricle contracts. In a normal mitral valve, the geometry of the mitral valve ensures the cusps overly each other to preclude the regurgitation of blood during left ventricular contraction and thereby prevent elevation of pulmonary vascular pressures and resultant symptoms of shortness of breath. Studies of the natural history of mitral regurgitation have found that totally asymptomatic patients with severe mitral insufficiency usually progress to severe disability within 5 years. Mitral valve regurgitation requires correction.

[0004] At present the treatment consists of either mitral valve repair or replacement, particularly suitable when one of the mitral cusps has been severely damaged or deformed. Both methods require open heart surgery.

[0005] Replacement can be performed with either mechanical or biological valves. The mechanical valve carries the risk of thromboembolism and requires anticoagulation with all of its potential hazards, whereas the biological prosthesis suffers from limited durability. Another hazard with replacement is the risk of endocarditis. These risks and other valve related complications are greatly diminished with valve repair.

[0006] Mitral valve repair is theoretically possible if the mitral valve leaflets are structurally normal but fail to appropriately coapt because of annular dilatation and/or papillary muscle dysfunction. Various surgical procedures have been developed to improve coaptation of the leaflet and to correct the deformation of the mitral valve annulus and retain the intact natural heart valve function. These procedures generally involve reducing the circumference of the posterior mitral leaflet annulus (lateral annulus) where most of the dilatation occurs regardless of the process since the annulus of the anterior leaflet (septal annulus) does not generally dilate because it is anchored to the fibrous skeleton at the base of the heart. Such techniques generally known as annuloplasty typically suture a prosthesis around the base of the valve leaflets shortening the lateral annulus to reshape the mitral valve annulus and minimize further dilation. Different types of prosthesis have been developed for use in such surgery. In general, prostheses are annular or partially annular shaped and may be formed from rigid or flexible material.

[0007] While these methods have been able to successfully treat mitral regurgitation, they have not been without problems and potential adverse consequences. For example, mitral valve annuloplasty fixes the posterior mitral leaflet in a systolic conformation and effectively reduces the mitral valve to a monocusp. In particular the annuloplasty ring prevents the dynamic orifice action of the mitral annulus in diastole and systole.

[0008] Miller and associates (J Thorac Cardiovasc Surg 2002;123:881-888; J Heart Valve Disease 2002;11:2-10) studied an open-chest surgical approach of septal-lateral annular cinching with sutures to treat acute ischemic mitral regurgitation. They disclose that a septal-lateral transannular suture was anchored to the midseptal mitral annulus and extermalized to a tourniquet through the midlateral mitral annulus and left ventricular wall. It is experimentally concluded that reduction in mitral annular septal-lateral dimension abolished acute ischemic mitral regurgitation in normal sheep hearts while allowing near-normal mitral annular and posterior leaflet dynamic motion.

[0009] In current practice mitral valve surgery requires an extremely invasive approach that includes a chest wall incision, cardiopulmonary bypass, cardiac and pulmonary arrest, and an incision on the heart itself to gain access to the mitral valve. Such a procedure is expensive, requires considerable time, and is associated with high morbidity and mortality. Due to the risks associated with this procedure, many of the sickest patients are denied the potential benefits of surgical correction of mitral regurgitation. In addition, patients with moderate, symptomatic mitral regurgitation are denied early intervention and undergo surgical correction only after the development of cardiac dysfunction. Furthermore, the effectiveness of such procedures is difficult to assess during the procedure and may not be known until a much later time. Hence, the ability to make adjustments to or changes in the prosthesis function to obtain optimum effectiveness is extremely limited. Correction at a later date would require another open heart procedure.

[0010] In an attempt to treat mitral regurgitation without the need for cardiopulmonary bypass and without opening the chest, catheter based methods have been devised to repair the valve or place a correcting apparatus for correcting the annulus relaxation. U.S. Pat. No. 6,391,054, entire contents of which are incorporated herein by reference, discloses an expandable annuloplasty ring which may be expanded in situ with an inflatable balloon, wherein the ring includes a solid core of non-elastic material for plastically retaining its shape and a discontinuity positioned at some point of the ring. As discussed before (J Heart Valve Disease 2002;11:2-10),

an annuloplasty ring tend to perturb mitral annulus dynamic motion and undesirably limit posterior leaflet excursion.

[0011] One approach to ensure coaptation of the leaflets is by stapling their leading edges together. U.S. Pat. No. 6,575,971, entire contents of which are incorporated herein by reference, discloses a medical device system comprising a guide catheter and a leaflet fastening applicator, the guide catheter having suitable dimensions for deployment and insertion percutaneously into a human heart in a vicinity of a heart valve, the leaflet fastening applicator having a size allowing insertion through the guide catheter and being capable of holding portions of opposing heart valve leaflets, wherein the fastening applicator comprises a pair of grasping-elements adapted for holding and engaging the portions of opposing heart valve leaflets together and for suturing or applying energy to fasten the portions, in which heart valve leaflets can be captured and securely fastened, thereby improving coaptation of the leaflets and improving competence of the valve. The durability of this procedure in the absence of a supporting annuloplasty remains to be seen.

[0012] U.S. Pat. No. 6,537,314, entire contents of which are incorporated herein by reference, discloses a mitral annuloplasty and left ventricle restriction device transvenously advanced and deployed within the coronary sinus, wherein the device places tension on adjacent structures, reducing the diameter and/or limiting expansion of the mitral annulus. Attempts at reducing the circumference of the lateral mitral annulus via the coronary sinus tend to freeze the posterior leaflet and prevent the dynamic motion of the mitral annulus.

[0013] Further, U.S. Patent Application 2002/0183836 published on Dec 5, 2002, entire contents of which are incorporated herein by reference, discloses an apparatus for reducing mitral regurgitation including a bendable elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the elongated body being adjustable between a first configuration adapted to be delivered into the coronary sinus and a second configuration adapted to exert a force onto the posterior annulus. However, a constant force onto the posterior annulus tends to limit posterior leaflet excursion.

[0014] U.S. Patent Application 2002/0087173 published on July 4, 2002, entire contents of which are incorporated herein by reference, discloses a device implantable in the coronary sinus of the heart to particularly encircle the mitral valve annulus and exerts a substantially radially inward force to the mitral valve to restore mitral valve annulus geometry.

[0015] None of the aforementioned inventions discloses a method for effecting a suitable approximation of the septal and lateral annulus of the mitral valve by a device compressing the right atrium against an anchoring point within the coronary sinus.

SUMMARY OF THE INVENTION

[0016] In general, it is an object of the present invention to provide a method and a device which is deployed in the coronary sinus and right atrium for effecting a 5-10 mm approximation of the septal annulus and lateral annulus of the mitral valve and promote coaptation of the mitral leaflets and dynamic function of the mitral valve annulus. Key to the method of the invention is appreciation that the anterior leaflet of mitral valve is not in same plane as tricuspid valve but sits close to the base of a heart and can be compressed from the right atrial side by applying pressure on the atrial septum in certain particular locations.

[0017] Some aspects of the invention relate to a device system for treating mitral regurgitation comprising an elongate element having a first end member and an opposite second end member, wherein the first end member is deployed in a coronary sinus and the second end member is deployed in a right atrium sized and configured for effecting an approximation of a septal annulus and a lateral annulus of the mitral valve. In one embodiment, the approximation is between about 1 and 20 mm, preferably between about 5 and 10 mm.

[0018] In some preferred embodiment, the first end member of the elongate element is configured bendable that enables anchoring the first end member in the coronary sinus. In another embodiment, the first member is connected to the second end member of the elongate

element by a ratchet system that is configured to allow approximation of the first and second members.

[0019] In one aspect, the elongate element is made of a resilient material and has a preformed semi-circular configuration or made of nitinol. In another aspect, the element has various resilience properties along the elongate element or comprises an adjustable cable running through a hollow resilient tubing.

[0020] In operations, the device system of the invention comprises a sheath and an introducer, wherein the elongate element is releasibly coupled to the introducer inside the sheath during a sheath delivery phase percutaneously.

[0021] Some aspects of the invention relate to a method for effecting an approximation of a septal annulus and a lateral annulus of a mitral valve comprising: (a) providing a device having an elongate element and an introducer within a catheter sheath, wherein the elongate element comprises a first end member and an opposite second end member; (b) delivering the catheter sheath endoluminally to a location adjacent the mitral valve; (c) deploying the first end member of the element out of the sheath and placing the first end member in a coronary sinus; and (d) deploying the second end member of the element out of the sheath and placing the second end member in a right atrium. In one embodiment, the step of deploying the second end member is carried out by placing the second end member at extent of the tendon of Todaro in the right atrium.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] Additional objects and features of the present invention will become more apparent and the invention itself will be best understood from the following Detailed Description of the Exemplary Embodiments, when read with reference to the accompanying drawings.

[0023] FIG. 1 shows a cutaway schematic of the heart showing the chambers and the spatial relationships of the various anatomical features discussed in the invention.

[0024] FIG. 2 shows a diagram of the triangle of Koch within the right atrium.

[0025] FIG. 3 shows a diagram of the heart showing relation of coronary sinus and anterior mitral annulus on a lateral annulus side.

[0026] FIG. 4 shows anatomic aspects of the right atrium, as seen at operation.

[0027] FIG. 5 shows a diagram of the right heart and planes of tricuspid valve and mitral valve.

[0028] FIG. 6 shows one embodiment of a device with compression members applying pressure to lateral annulus and septal annulus according to the principles of the present invention.

[0029] FIG. 7 shows a diagram of the compression device placed around the lateral annulus and septal annulus of the mitral valve.

[0030] FIG. 8 shows a diagram of a cutaway heart showing a first compression member of the device in coronary sinus exerting force toward the septal annulus while a second compression member of the device in right atrium on tendon of Todaro exerting force toward lateral annulus.

[0031] FIG. 9 shows one embodiment of the medical device having a ratchet system.

[0032] FIG. 10 shows one embodiment of the medical device having a septal-lateral annular cinching system.

[0033] FIG. 11 shows one embodiment of the medical device having an elongate element comprising an adjustable cable running through a hollow resilient tubing.

[0034] FIG. 12 shows a diagram of the septal-lateral annular cinching device placed across the lateral annulus and septal annulus of the mitral valve.

[0035] FIG. 13 shows a four-chamber tomographic view through the aortic root showing the location of the second compression member of the compression device in relation to the interventricular and atrioventricular septum.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

[0036] FIGS. 1-13 show a device system and methods for treating mitral regurgitation by approximating the septal and lateral (clinically referred to as anterior and posterior) annuli of the mitral valve. While the description sets forth various embodiment specific details, it will be appreciated that the description is illustrative only and should not be construed in any way as limiting the invention. Furthermore, various applications of the invention, and modifications thereto, which may occur to those who are skilled in the art, are also encompassed by the general concepts described below.

[0037] The present invention provides an improved apparatus and method to treat mitral regurgitation. Of particular importance and a salient aspect of the present invention allows mitral regurgitation to be treated without resorting to open heart surgery. This is rendered possible not only by the realization that the coronary sinus of a heart is near to and at least partially encircles the lateral mitral valve annulus but more importantly the mitral valve lies in a plane lateral to the right atrial tricuspid valve and as such the triangle of Koch and in particular the tendon of Todaro up to the point of the membranous septum overlies the septal annulus of the mitral valve. Therefore, the device of the present invention may be employed by introduction into the coronary sinus and approximating the extent of the tendon of Todaro in the right atrium to advantageously affect the geometry of the mitral valve annulus by bringing the lateral annulus

and septal annulus of the mitral valve into closer proximity and to ensure coaptation of the leaflets.

[0038] FIG. 1 shows a cutaway schematic of the heart showing the chambers and the spatial relationships of the various anatomical features discussed in the invention. The heart 10 comprises a pulmonary valve 11, an aortic valve 12, an atrioventricular (also known as tricuspid) valve 13, and a mitral valve 14 when the cardiac valves are in a filling phase (diastole). An opening 15 of coronary sinus (also known as ostium) is also shown in FIG. 1.

[0039] FIG. 2 shows a diagram of the triangle of Koch within the right atrium while FIG. 3 shows a diagram of the heart showing relation of coronary sinus and anterior mitral annulus on a lateral annulus side. The triangle is defined by the tendon of Todaro 18, the orifice of the coronary sinus 20 and the tricuspid annulus 16. Blood from peripheral circulation returns to the right atrium 30 of the heart 10 via superior vena cava 22 or inferior vena cava 23. The diagram shows the relationship of the AV node 19 and AV bundle 17 to triangle of Koch. The membranous septum 21 lies at about the end of Todaro 18.

[0040] FIG. 4 shows anatomic aspects of the interior of the right atrium 30, as seen at operation. The membranous septum 21 is easily visualized. The tricuspid valve comprises an anterior leaflet 27, a posterior leaflet 28, and a septal leaflet 29. Indentation 26 of anterior (septal) mitral annulus is shown at close to the membranous septum 21.

[0041] FIG. 5 shows a diagram of the right heart, aorta 61, right coronary 62, fossa ovalis 53, and planes of the tricuspid valve and the mitral valve. The plane 64 of the mitral valve attachment (dashed line) corresponds to the atrial edge of the muscular atrioventricular septum 51 and the inferior edge of the membranous septum 21. The plane 64 of the mitral valve (dashed line) differs from the plane 63 of the tricuspid valve (solid line).

[0042] FIG. 6 shows one embodiment of a device with compression members applying pressure to lateral annulus and septal annulus according to the principles of the present invention. Some aspects of the invention provide a device system for treating mitral regurgitation comprising an elongate element 25 having a first end member 25A and an opposite second end member 25B, wherein the first end member 25A is deployed in a coronary sinus 20 through an opening 15 of the coronary sinus, and the second end member 25B is deployed in a right atrium 30 sized and configured for effecting an approximation of a septal annulus and a lateral annulus of the mitral valve 14. The second end member 25B is preferably placed at about the tendon of Todaro.

[0043] FIG. 7 shows a diagram of the compression device 25 placed around the lateral annulus and septal annulus of the mitral valve. The first end member 25A of the device 25 is inserted into the coronary sinus of the heart and the opposite second end member 25B of the device rests within the right atrium 30 along or about the tendon of Todaro 18 and extends to at least the membranous septum 21 of the tricuspid valve 13. Referring to FIG. 7, there is illustrated a schematic view of the heart 10, having a compression device 25 positioned therein. The heart 10 generally comprises a right atrium 30, in communication with the superior vena cava 22 and inferior vena cava 23. The left ventricle 33 is positioned below the left atrial appendage 35. Relevant portions of the coronary vasculature include the coronary sinus 20, which extends from the ostium 15 to the junction 34 of the coronary sinus and the great cardiac vein 32. There may be anastomotic connections 69 between the great cardiac vein 32 and the middle cardiac vein 31, as is well known to one skilled in the art.

[0044] Because the coronary sinus approximates the lateral (posterior) annulus of the mitral valve and the tendon of Todaro approximates the septal (anterior) annulus of the mitral valve, the device encircles approximately one half of the mitral valve annulus. The apparatus is then adapted to deform the underlying structures i.e. the septal annulus and lateral annulus of the mitral valve in order to move the posterior leaflet anteriorally and the anterior leaflet posteriorly and thereby improve leaflet coaptation and eliminate mitral regurgitation.

[0045] The device or apparatus may be implanted in the coronary sinus and right atrium using only percutaneous techniques similar to the techniques used to implant cardiac leads such as pacemaker leads. The present invention provides a system and method for treating mitral regurgitation caused by ischemic and dilated cardiomyopathy. The resilient member by its nature prevents further dilatation of the mitral annulus and also inhibits diastolic ventricular dilatation in the region of the member and as such prevents progressive ventricular dilatation and therefore helps treat dilated cardiomyopathy. In one embodiment, the device system includes the resilient member and an elongated introducer coupled to the resilient member but easily disconnected. The introducer is flexible. This permits it to advance the resilient member into the heart and into the coronary sinus through the coronary sinus ostium. To promote guidance the system may further include an elongated sheath which straightens the resilient member which is first advanced into the coronary sinus. Then the resilient member and introducer are moved through the sheath until the resilient member is in position within the coronary sinus at approximately the midpoint of the lateral annulus. The sheath may be partially retracted to permit the resilient member to assume its preformed arch or semi-circular configuration and approximate the interatrial septum beyond the coronary ostium along the tendon of Todaro up to and beyond the membranous septum. Once the resilient member is properly positioned the introducer is then decoupled from the resilient member and retracted through the sheath. The procedure is completed by the retraction of the sheath. As a result, the resilient member is left within the coronary sinus and right atrium to exert inward pressure on the septal and lateral mitral annulus to restore valve geometry and eliminate mitral regurgitation.

[0046] In a preferred embodiment the distal 5 mm and proximal 5 mm of the resilient member may be connected by a movable joint which has a more flexed preformed configuration or may be so adjusted by a fine cable system running through a hollow resilient member. This enables adjustments to be made through the prosthesis during deployment to obtain optimum effectiveness with respect to eliminating mitral regurgitation. FIG. 11 shows one embodiment of the medical device having an elongate element 71 comprising an adjustable cable 76 running

through a hollow resilient tubing 74. The elongate element 71 comprises a first end member 71A to be inserted within a coronary sinus and a second end member 71B to be placed at the right atrium. The semi-circular (or appropriately curved) configuration of the elongate element 71 is adjusted by suitably pulling the cable 76 from a first configuration 72 to a second configuration 73. The elongate element provides a stopper 75 at the end of the first end member 71A and an adjustable stopper 77 at the end of the second end member 71B. By way of example, the second configuration 73 has a smaller radius of curvature and a longer external distance D_2 when compared to the first configuration 72 with an external distance D_1 that is shorter than D_2. The resilient member or tubing may be made of elastic material, such as silicone, polyurethane, shape-memory metal, shape-memory polymer, nitinol or the like.

[0047] FIG. 8 shows a diagram of a cutaway heart showing a four-chamber view and a first compression end member 25A of the device in coronary sinus 20 exerting force toward the lateral annulus while a second compression end member 25B of the device in the right atrium on tendon of Todaro (or adjacent to tendon of Todaro) exerting force toward anterior annulus. The tomographic view of FIG. 8 shows the relative locations of an interatrial septum 44 (between a right atrium 30 and a left atrium 45), an atrioventricular septum 51, an interventricular septum 52 (between a right ventricle 46 and a left ventricle 33), a left lower pulmonary vein 47 and a right lower pulmonary vein 48. FIG. 8 also shows the anatomic location of septal insertion 50 of the mitral valve and fossa ovalis 53.

[0048] The compression device 25 is a longitudinal dimension having a semi-circular or curved configuration when deployed for encircling at least half of the mitral valve annulus and exerting an inward pressure on not only the lateral (posterior) annulus but also on the septal (anterior) annulus. The inward pressure brings the lateral annulus into closer proximity with the septal annulus. This serves to essentially restore the mitral valve geometry and to promote effective valve sealing action through coaptation of the leaflets to eliminate mitral regurgitation and preserve the dynamic function of the mitral annulus during systole and diastole.

[0049] FIG. 10 shows one embodiment of the medical device having a septal-lateral annular cinching system while FIG. 12 shows a diagram of the septal-lateral annular cinching device placed across the lateral annulus and septal annulus 78 of the mitral valve. In one particular embodiment as shown in FIG. 12, a cinching device 57 for effecting the condition of septal to lateral annular cinching includes a first end member 57A having a cross-sectional dimension for being deployed within the coronary sinus 20 of the heart 10 and a second end member 57B approximating the extent of the tendon of Todaro 18 within the right atrium 30. A cinching means for shortening the distance between the end members 57A and 57B is attachably connected to both end members. By appropriate cinching, a suitable approximation of the septal and lateral annuli of the mitral valve is effected. This may be done surgically from lateral wall of heart 10 to inside of right atrium 30.

[0050] In a particular aspect of the present invention, the resilient member may be made of nitinol or other suitable material and takes on a preformed configuration when deployed but is resilient and permits straightening during implantation. Once implanted in the coronary sinus and right atrium the member exerts an inward compressive force on the septal and lateral annulus.

[0051] FIG. 9 shows one embodiment of the medical device having a ratchet system. In such an embodiment, the first end member (i.e., coronary sinus member) 55A of the medical device 55 and the second end member (i.e., right atrial member) 55B may be distinct but connected by a ratchet system with a plurality of teeth 36 which allows approximation of the two members to a desired degree. When these two members are approximated the septal and lateral annulus will of necessity also be approximated. The approximation is desirably between about 1 and 20 mm, preferably between about 5 and 10 mm. A ratchet system is well known to one skilled in the art.

[0052] FIG. 10 shows an alternate embodiment of the medical device having a septal-lateral annular cinching system enabling effecting a suitable approximation of the septal annulus

and lateral annulus of the mitral valve. The device 56 comprises a first end member 56A and a second end member 56B, wherein the first end member has a first end stopper 37 and the second end member has an axially adjustable second end stopper 38. By moving the second end stopper 38 toward (as shown by an arrow 39) the first end stopper 37 along the cinching wire 56, the interatrial septum 44 is moved toward the coronary sinus 20 that translates to approximation of the septal annulus and lateral annulus of the mitral valve. In another embodiment, a first short pledget-like member 40 may be introduced into the coronary sinus which will direct the penetrating wire 58 to perforate the left atrial wall 41 of the coronary sinus 20 and enter the left atrium. This wire can then be directed to perforate at a point 43 on the interatrial septum 44 just lateral to the tendon of Todaro and engage in a receiving pledget-like member 42 on the right atrial side of the intra-atrial septum. Once engaged the wire can be cinched so that the septal and lateral annulus of the mitral valve are brought into closer proximity and the reduction in mitral regurgitation observed.

[0053] FIG. 13 shows a four-chamber tomographic view through the aortic root 65 showing the location of the second compression end member 25B of the compression device in relation to the interventricular septum 52 and atrioventricular septum 51. This is to more particularly point out the novelty of the current approach of percutaneous reduction of anterior-posterior diameter of a mitral valve by positioning a first end member of a compression device inside the coronary sinus while placing a second end member at the extent of the tendon of Todaro 18 in the right atrium 30. Some aspects of the present invention provide a method for effecting an approximation of a septal annulus and a lateral annulus of a mitral valve comprising: (a) providing a device having an elongate element and an introducer within a catheter sheath, wherein the elongate element comprises a first end member and an opposite second end member; (b) delivering the catheter sheath endoluminally to a location adjacent the mitral valve; (c) deploying the first end member of the element out of the sheath and placing the first end member in a coronary sinus; and (d) deploying the second end member of the element out of the sheath and placing the second end member in a right atrium.

[0054] From the foregoing description, it should now be appreciated that a device system and methods for effecting percutaneous reduction of anterior-posterior diameter of a mitral valve has been disclosed. While the invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications and applications may occur to those who are skilled in the art, without departing from the true spirit and scope of the invention, as described by the appended claims.